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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,464	05/03/2007	Marsha A. Moses	C1285.70006US01	5882

23628 7590 11/25/2009

WOLF GREENFIELD & SACKS, P.C.
600 ATLANTIC AVENUE
BOSTON, MA 02210-2206

EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
11/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,464	MOSES ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6,7,9-16 and 20-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6,7,9-16 and 20-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 13, 2009 has been entered.

2. Claims 1, 3, 4, 6, 7, 9-16 and 20-43 are pending.

Claims 1, 4, 7 and 9 have been amended.

Claims 38-43 have been added.

Claims 1, 3, 4, 6, 7, 9-16 and 20-43 are examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Grounds of Rejection

Claim Rejections - 35 USC § 102

4. The rejection of claims 1, 3, 4, 6, 7, 9-16 and 20-37 under 35 U.S.C. 102(e) as being anticipated by Berger et al./ U.S. Patent Application Publication number 2003/0148410 A1 (filed November 21, 2002) is withdrawn in light of the amendments to claims 1, 4, 7 and 9 submitted November 13, 2009.

Maintained and New Grounds of Rejection

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 38-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Berger et al./ U.S. Patent Application Publication number 2003/0148410 A1 (filed November 21, 2002). Berger discloses methods for detecting and characterizing human colon cancers implementing assays determining the level

of a marker protein, see abstract; and sections 0276-0299 beginning on page 31. Colon cancer is a cancer of epithelial origin and claims 38-43 do not exclude colon cancer. Table 1 lists all of the markers disclosed in the invention including ADAM 12, art known as a disintegrin and metalloproteinase domain 12 or meltrin alpha, see page 4, section 0060 and the table. The ADAM 12 marker can be detected blood fluids, stool, colon lavage fluids, lymph fluids and urine via an antibody which is labeled by several means, see page 3, section 0048; page 10, section 0114; and page 33, section 0300.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The rejection of claims 1, 3, 4, 6, 7, 9-16, 20-37 and new claims 38-43 under 35 U.S.C. 103(a) as being unpatentable over Iba et al. (Am J. Pathol. 154(5):1489-501, May 1999), and further in view of Berger et al./ U.S. Patent Application Publication number 2003/0148410 A1 (filed November 21, 2002) is maintained and made.

Applicants argue "[o]ne of ordinary skill in the art would not have substituted the tumor tissues samples taught by Iba...with the biological fluids

taught by Berger...because the results of substitution would not have been predictable.", see Remarks submitted November 13, 2009, page 8. Applicants' arguments depend upon the examples of basic requirements of a *prima facie* case of obviousness set forth in MPEP 2143 and a Supreme Court decision. Applicants'aver the Examiner has failed to establish to meet the said requirements, see Remarks, page 10. Applicants continually argue the Iba reference provides no reason or motivation to one of ordinary skill in the art to measure the expression levels of ADAM 12-S in a biological sample because it is present in both normal and tumor tissue, see page 11 of the Remarks. Moreover, Applicants assert a skilled artist would not have any expectation of success in detecting ADAM 12-L in the biological samples of instant claims. These arguments and points of view have been carefully considered, but found unpersuasive.

As noted in the Final Action mailed May 14, 2009 Applicants' arguments address particular forms of ADAM 12 and are moot because the claims do not delineate any particular species of the protein, see page bridging paragraph of pages 5 and 6 of said Action. The claims broadly read on "ADAM 12". This term encompasses all types of ADAM 12, hence the claims are not restricted to any particular form of the protein as noted by Applicants in their Remarks, see page 11. Applicants reiterate rationales set forth in MPEP 2143 and the Examiner concurs. Berger provides the detection of ADAM 12 and absent any scientific evidence to the contrary, presumably all types of ADAM 12 are

detected with success and predictability giving impetus to one of ordinary skill in the art to substitute one known element (i.e. biological samples) for another. The Examiner has weighed the teachings of both references and given the range of biological samples assayed in Berger and the protein measured, the expectation of success in detecting ADAM in a multitude of biological samples of the instant claims is expected.

Iba teaches "[t]he distribution of ADAM 12 in... 37 human carcinomas compared with the normal counterpart tissue... investigated by immunohistochemistry", see page 1493, Results section. These tissue specimens are from human carcinomas comprising ductal breast carcinoma, adenocarcinoma of the colon and rectum, squamous cell carcinoma of the lung and adenocarcinoma of the stomach, see page 1490, Tissue samples...section. Adjacent nontumorous tissues were also investigated. "All 15 cases of breast carcinomas exhibited intense ADAM 12 immunoreactivity (Figure 1A) using several different antibodies, whereas in normal breast tissue, only a few scattered luminal cells of the ducts exhibited ADAM 12 immunoreactivity (Figure 1E)", see page 1493, Results section. Labeled monoclonal antibodies to human ADAM 12 were implemented in the immunohistochemistry assays, see page 1490, Antibodies and Immunohistochemistry...sections; and Figure 1 on page 1494. "Breast carcinoma tissue appeared to contain more ADAM 12-L transcript than normal breast tissue (Figure 1G)", see bridging sentence of

columns 1 and 2 on page 1493. Iba does not teach the disclosed method, wherein a biological sample assayed for ADAM 12 is urine, blood or serum.

However, Berger teaches urine and blood fluids as a biological sample to test for the presence or absence of ADAM 12, see page 3, section 0048; and page 8, section 0069. Blood and sera are regarded by the Examiner as blood fluids, It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of both documents assay a plethora of biological samples for ADAM 12, particularly a urine sample, blood or serum. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Berger. Berger implemented a diagnostic assay using urine, blood fluids as test samples and ADAM 12 is clearly and definitively associated with cancer, see Berger, page 3, section 0048 and page 33, section 0300; and Iba, abstract.

The combination of the references meets all the requirements for a establishing a *prima facie* case of obviousness. There is some suggestion or motivation in the references themselves and/or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. The teaching or suggestion to make the claimed combination and the reasonable expectation of success has been found in the prior art and not based on Applicants' disclosure. The Examiner has met all the criteria *prima facie* obvious. The rejection is maintained and made for reasons of record and set forth herein.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1, 3, 4, 6, 7, 9-16 and 20-43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-24, 42 and 44 of copending Application No. 12/085,134/ U.S. Patent Application No. 20090215102 (filed April 14, 2009). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims read detecting ADAM 12 in biological samples.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
19 November 2009
/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643